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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,824	07/14/2003	Lieping Chen	07039-427001 / MMV-02-228	7199

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EXAMINER	
OUSPENSKI, ILIA I	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/619,824	CHEN ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 – 8 and 10 – 34* is/are pending in the application.

4a) Of the above claim(s) *11 – 16, 22, 29 – 31, and 33 – 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 – 8, 10, 17 – 21, 23 – 28, and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/7/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment/remarks, filed on 12/07/2006, are acknowledged.

Claim 9 has been cancelled.

Claims 1 – 8 and 10 – 34 are pending.

Claims 11 – 16, 22, 29 – 31, and 33 – 34 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions/Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 03/27/2006.

Claims 1 – 8, 10, 17 – 21, 23 – 28, and 32 are under consideration in the instant application, as they read on the elected invention drawn to methods for treating systemic lupus erythematosus using a 4-1BB agonist antibody.

2. This Office Action will be in response to Applicant's amendment and arguments, filed on 12/07/2006.

The rejections of record can be found in the previous Office Action, mailed on 06/07/2006.

The objections and rejections of record have been withdrawn in view of Applicant's amendment and arguments, except as set forth herein.

3. Applicant's IDS, filed 12/07/2006, is acknowledged, and has been considered.

4. Applicant's argument regarding the claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. In view of Applicant's arguments, the provisional application USSN 60395,896 appears to provide adequate support under 35 U.S.C. 112 for subject matter claimed in the instant application.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6, 8, and 21 stand rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 6 and 21 are indefinite in the recitation of antibody "2A" because its characteristics are not known.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that characteristics of the antibody 2A are provided e.g. in Example 1.

This is not found persuasive, because the only characteristic of antibody 2A found in Example 1 is it "was generated as previously described." This is not deemed

as sufficient to make one of ordinary skill in the art reasonably apprised of the metes and bounds of the invention.

B. Claim 8 is indefinite in the recitation of "Gr-1," because its characteristics are not known.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the specification defines Gr-1 as "a myeloid differentiation antigen expressed on cells of the myeloid lineage, and serves as a marker for granulocyte maturation" (page 16, lines 17-21).

This is not found persuasive, because one of skill in the art is aware that numerous myeloid differentiation antigens are expressed on cells of the myeloid lineage, and many more may be discovered in the future. Furthermore, the phrase "serves as a marker for granulocyte maturation" is itself vague and indefinite, because the criteria for a molecule being a "marker" have not been defined, and it is unclear which stage or stages of granulocyte maturation are encompassed by the phrase.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 6 and 21 stand rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention.

It is apparent that the "2A" antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line or a hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that methods for producing antibodies were routine in the art, and that Applicant's specification teaches methods of making antibodies against 4-1BB and for using such antibodies to deplete double negative T cells.

This is not found persuasive, because even while a skilled artisan may be enabled to produce antibodies against 4-1BB using methods well known in the art and the direction provided in Applicant's specification, the skilled artisan will not arrive at the specific recited antibody "2A," because each antibody is unique, as is well known to one skilled in the art.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

9. Claims 1 – 3, 7 – 8, 10, 17 – 18, 23 – 28, and 32 stand rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for methods employing a 4-1BB agonist antibody, with or without an antibody that binds to GR-1, does not reasonably provide enablement for methods employing a generically recited "4-1BB agonist." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

It is noted that the elected invention is limited to 4-1BB agonist antibodies; however, the rejection is set forth with regard to the full scope of the generic claims as presently recited.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the specification teaches that 4-1BB agonists include 4-1BB ligand (4-1BBL) and functional fragments thereof, in addition to an antibody or functional fragments of an antibody.

While not addressing the issue of whether the specification is enabling for 4-1BB ligand or functional fragments thereof, it is noted that the claims, as presently recited, are not limited to agonists which are antibodies and 4-1BBL or functional fragments thereof.

Applicant further argues that the specification teaches how to test potential 4-1BB agonist molecules for the ability to deplete double negative T cells.

In response, given the unpredictability of the art, as addressed in the previous Office Action, and given the general guidance provided in the specification and limited working examples, the experimentation left to those skilled in the art in searching for 4-1BB agonists, other than anti-4-1BB agonist antibodies, is unnecessarily, and improperly, extensive and undue.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1 – 5, 17 – 20, 23 – 27, and 32 stand rejected under **35 U.S.C. 102(b)** as being anticipated by Kang et al. (US Patent No. 5,928,893; 1999; reference AD on IDS filed 09/17/2004; see entire document).

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that Kang et al. do not disclose all the limitations of the instant claims, such as a 4-1BB agonist, because the antibody taught by Kang et al. is an antagonist antibody. Applicant further argues that Kang et al. do not teach that administration of the antibody results in the depletion of double negative T cells.

This is not found persuasive, because since Kang et al. teach administering an antibody of the same specificity (4-1BB) to treat the same disease (autoimmune disease), all of its relevant functional properties, such as being an agonist vs. antagonist, and the cellular mechanisms of action, are inherently the same. The fact that Kang et al. might not have been aware that the antibody they teach administering for treatment of autoimmune disease is an agonist, or of the cellular mechanisms of its action, does not negate the rejection. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

12. Claims 1 – 5, 10, 17 – 20, 23 – 28, and 32 stand rejected under **35 U.S.C. 102(a) and 102(e)** as being anticipated by B. Kwon (US Patent No. 6,303,121; 2001; reference AF on IDS filed 09/17/2004; see entire document).

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that Kwon does not disclose all the limitations of the instant claims, such as a 4-1BB agonist, or that administration of the antibody results in the depletion of double negative T cells. Applicant further argues that if two antibodies bind to the same target, it does not necessarily mean that both antibodies have the same effect.

In response, while it is true that two antibodies that bind to the same target do not necessarily have the same effect, in the present case, when two antibodies bind to the same target, and are administered to the same patient population to treat the same disease (SLE), it follows that the two antibodies inherently have the same effect.

The fact that Kwon might not have been aware of the cellular mechanisms of action of his anti-4-1BB antibody does not make the instant claims novel. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims. The rejection or record is incorporated by reference herein, as if reiterated in full.

13. Conclusion: no claim is allowed.

14. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ILIA OUSPENSKI, Ph.D.
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Art Unit 1644

February 19, 2007

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PRIMARY EXAMINER
TC 1600
2/21/07